MAR 21 2002

510K Summary of Safety and Effectiveness

1. Sponsor Name — Corniche. L.L.C.
   Address: 7 Main St.
   Essex Junction, VT 05452
   Telephone: 802 878 0900
   Fax: 802 878 0425
   Contact Individual: Stuart Smyth

2. Device Name

   Proprietary Name: SAFYRE Sling
   Common/Usual Name: Surgical Mesh
   Classification Name: Surgical Mesh

3. Identification of Predicate or Legally Marketed Device

   - SPARC Sling System – K 011251 manufactured by American Medical Systems
   - Tension Free Vaginal Tape (TVT) System – K 974098 manufactured by Ethicon (J&J)
   - BioSling – K010533 – manufactured by InjectX Inc.

4. Device Description

PROMEDON's Sling, SAFYRE, is manufactured with biocompatible silicone elastomers and polypropylene. It is a permanent implant and is offered as a single use sterile product.

Safyre consists of a pierced polypropylene mesh between two silicone columns that are made of multiple cone-shaped soft tissue anchors. These units are the basis of the self anchoring system. The polypropylene mesh lies on the mid-urethra and the interconnective tissue grows among the perforations between the vaginal flap and the urethra, which leads to integration of the implant without a loss of vascularization between the bladder and the vagina. The two columns are fixed to the abdominal fascia. This self anchoring is enough to keep the sling in its place when there is an important muscular activity, such as coughing or other strains.

5. Intended Use

Safyre Sling is to be permanently implanted in women, for the treatment of stress urinary incontinence grades II and III (due to bladder hypermobility and/or Intrinsic Sphincter Deficiency) acting as a urethral support.

6. Comparison of Technological Characteristics

All of the devices are indicated for permanent implantation for the treatment of stress urinary incontinence grades II and III acting as a urethral support. All of the devices are made of the same or similar materials and are supplied with reusable insertion components.

The SAFYRE Sling is substantially equivalent to the predicate devices. The intended use, technological characteristics of the device materials and design of the SAFYRE Sling support the concept of substantial equivalence.

7. Performance Testing

Bench testing and biocompatibility testing was performed on the SAFYRE Sling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Promedon
% Ms. Debbie Iampietro
QRC Associates
7 Tiffany Trail
HOPKINTON MA 01748

SEP 28 2012

Re: K020007
Trade/Device Name: Safyre Sling System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: December 30, 2001
Received: January 4, 2002

Dear Ms. Iampietro:

This letter corrects our substantially equivalent letter of March 21, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

A.3. Statement of Indications for Use

Applicant: PROMEDON S.A.

510(k) Number (if known): K020007

Device Name: **SAFYRE - SLING FOR URINARY INCONTINENCE**

Indications For Use:

Safyre Sling is to be permanently implanted in women, for the treatment of stress urinary incontinence grades II and III (due to bladder hypermobility and/or Intrinsic Sphincter Deficiency) acting as a urethral support.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription X (Per 21 CFR 801.109) OTC

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020007